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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/376,430	08/18/1999	PAUL A. MOORE	PF466P1	6501

22195 7590 05/20/2003

HUMAN GENOME SCIENCES INC  
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ROCKVILLE, MD 20850

EXAMINER
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O HARA, EILEEN B

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 05/20/2003

36

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/376,430

Applicant(s)

MOORE ET AL.

Examiner

Eileen O'Hara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 February 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 24-56, 59-61, 64-79, 81-83 and 85-104 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 24-54, 59, 103 and 104 is/are allowed.
- 6) ☒ Claim(s) 55, 56, 60, 61, 64-79, 81-83, 85-89, 91-95 and 97-102 is/are rejected.
- 7) ☒ Claim(s) 90 and 96 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \*   c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 35.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### **DETAILED ACTION**

#### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 19, 2003 has been entered.

#### ***Claims Status***

2. Claims 24-56, 59-61, 64-79, 81-83 and 85-104 are pending in the instant application. Claims 40-43, 47-56, 59-61, 64-76, 89, 95 and 100-102 have been amended and claims 57, 58, 62, 63, 80 and 84 have been canceled as requested by Applicant in Paper Number 34, filed February 19, 2003.

#### ***Information Disclosure Statement***

3. The sequences disclosed in the IDS filed December 20, 2002 (references AK-AN) have been considered to the extent that was possible absent an explanation of relevance or a sequence alignment.

#### ***Withdrawn Rejections***

4. The rejections of claims under 35 USC 112, second paragraph are withdrawn in view of Applicants' amendment.

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### *Claim Objections*

5. Claims 90 and 96 are objected to because of the following informalities: the word "the" should be inserted between the words "comprising" and "amino" to be grammatically correct. Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

- 6.1 Claims 88, 91-94, 97-99 and 102 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polypeptide of SEQ ID NO: 2 and for

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polypeptides consisting of fragments of SEQ ID NO: 2, and for polypeptides having homology to the polypeptide of SEQ ID NO: 2 that have specific activities, does not reasonably provide enablement for polypeptides comprising fragments of SEQ ID NO: 2 or for polypeptides having homology to the polypeptide of SEQ ID NO: 2 which do not have a specific function. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicants have amended many of the previously rejected claims to replace "comprising" with "consisting" language, or to recite a specific activity for the polypeptide homologs or polypeptides comprising fragments, therefore overcoming the rejection for those claims. However, the presently rejected claims either do not have an activity for the polypeptide as a

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limitation, for example claim 88, or recite a functional limitation but do not require any structure, for example claim 102. In claim 102 subpart (a), the polypeptide can have 1 or more amino acid residues substituted, deleted or added, in any combination, as long as the polypeptide transduces immune cell proliferation. Therefore, the claim encompasses any protein having any structure that can have this activity. The claim is a single means claim, i.e., where a means recitation does not appear in combination with another recited element of means, is subject to an undue breadth rejection under 35 U.S.C. 112, first paragraph. In re Hyatt, 708 F.2d 712, 714 - 715, 218 USPQ 195, 197 (Fed. Cir. 1983) (A single means claim which covered every conceivable means for achieving the stated purpose was held nonenabling for the scope of the claim because the specification disclosed at most only those means known to the inventor.). When claims depend on a recited property, a fact situation comparable to Hyatt is possible, where the claim covers every conceivable structure (means) for achieving the stated property (result) while the specification discloses at most only those known to the inventor. See M.P.E.P. 2164.08(a).

The specification is enabling for assays to determine if the claimed polypeptide variants have the activities of the polypeptide of SEQ ID NO: 2. However, the specification has not taught how to use polypeptides that do not have those activities. The rejection would be overcome if the claims were amended to recite sufficient structural and functional limitations.

6.2 Claims 88, 91-94, 97-99 and 102 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for reasons of record in the previous Office Action, Paper No. 26, at pages 6-8, and paper No. 31, at pages 5-6, and below.

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As discussed above, Applicants have amended many of the previously rejected claims to replace "comprising" with "consisting" language, or to recite a specific activity for the polypeptide homologs or polypeptides comprising fragments, therefore overcoming the rejection for those claims. However, because the presently rejected claims either do not have an activity for the polypeptide as a limitation, or recite a functional limitation but do not require any structure the claims do not have adequate written description.

Applicants traverse the rejection and assert that MPEP §2163 advises that the written description requirement is satisfied, "by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." Applicants submit that the full-length amino acid sequence of the claimed invention is disclosed and the specification also discusses the various consensus domains of the claimed protein as compared to its closest homolog, the IL-2 common gamma chain, thereby linking structure with function, and therefore one of skill in the art would know which domains of the claimed invention should remain untouched in order to generate the fragments and variants encompasses within the scope of the newly amended claims.

Applicants' arguments have been fully considered but are not deemed persuasive. The written description guidelines indicate that a representative species may be adequately described through its structure, through its functional characteristics, or through a combination of its structure and function. There is either no functional limitation in the claims or no structural limitation. The claims do not provide adequate structure or function to meet the written

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description guidelines. Therefore, the rejection is maintained. The rejection would be overcome if the claims were amended to recite sufficient structural and functional limitations.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 55, 56, 60, 61, 64-83, 85-87, 89, 95 and 100-102 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

55, 56, 60, 61, 64-83, 85-87, 89, 95 and 100-102 are indefinite because they either recite or depend from a claim encompassing a polypeptide which, for example in claim 55, "transduces immune cell proliferation". The word "transduce" is not an art accepted term as used in the claims and is therefore indefinite. Webster's Ninth New Collegiate Dictionary defines the word "transduce" as 1. To convert (as energy or a message) into another form, or 2. To bring about the transfer of (as a gene) from one microorganism to another by means of a viral agent.

### *Conclusion*

- 8.1 Claims 24-54, 59, 103 and 104 are allowed.
- 8.2 Claims 55, 56, 60, 61, 64-79, 81-83, 85-89, 91-95 and 97-102 are rejected.
- 8.3 Claims 90 and 96 are objected to.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312.

The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers Before Final filed by RightFax should be directed to (703) 872-9306.

Official papers After Final filed by RightFax should be directed to (703) 872-9307.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D.



Patent Examiner